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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/223,634	12/31/1998	RANDOLPH J. NOELLE	012712 - 652	1304

909 7590 10/21/2003

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EXAMINER	
GAMBEL, PHILLIP	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 10/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/223634	Applicant(s) NOELLE
	Examiner GAMBEL	Art Unit 1644

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 6/9/03

2a)☐ This action is **FINAL**. 2b)☑ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☑ Claim(s) _____ is/are pending in the application. 13-26

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☑ Claim(s) _____ is/are rejected. 13-26

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☑ The translation of the foreign language provisional application has been received.

15)☑ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☑ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

PAPER NO. 24

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission filed on 6/9/03 (Paper No. 23), has been entered.

Claims 18-26 are pending.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 18-25 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Lederman et al. (U.S. Patent No. 6,592,868) in view of Tung et al. (Immunology and Allergy Clinics of North America 10 (1) : 199-214 (1990), De Angelo et al. (J. Reprod. Immunol. 11: 41-53, 1987), Stull et al. (Cellular Immunology 117: 188-198 (1988) and Schieven(U.S. Patent No. 5,565,491).

Lederman et al. teach treating autoimmune diseases (e.g. column with 5C8-specific (i.e., gp39-specific / CD40 ligand-specific / CD40L-specific) antibodies, including monoclonal, chimeric and humanized antibodies (e.g. Detailed Description of the Invention on columns 6-8)(see entire document, including column 11, paragraph 5 and Claims). Lederman et al. Teach that such antibodies inhibiting T cell activation of B cells (e.g. Background of the Invention on columns 1-2; Summary of the Invention on column 2; see the first paragraph of the Detailed Description of the Invention on column 6 - column 7, paragraph 1).

Lederman et al. differs from the claimed invention by not disclosing that thyroiditis and/or oophoritis were the targeted autoimmune conditions.

Tung et al. review autoimmune conditions associated with testicular and ovarian functions, including oophoritis (See entire document, including Experimental Autoimmune Diseases of the Ovary on pages 206-210). Tung et al. teach that it was known at the time the invention was made that animal models of autoimmune oophoritis also developed autoimmune thyroiditis, gastritis, prostatis and epididymo-orchitis (see page 206, paragraph 3). Such autoimmune diseases of the ovary (as well as the testes) are associated with undesired antibody responses as well as presence of T helper cell types (e.g. CD4+ T cells Lyt1+).

De Angelo et al. similarly teach that it was known at the time the invention was made that oophoritis was associated with high circulating levels of undesired antibodies (see entire document, including Summary on page 41).

Stull et al. teach that it was known at the time the invention was made that autoimmune response associated with thyroiditis with autoantibodies and the important role of helper T cells (see entire document, including Abstract and Discussion). Also, Stull et al. teach prevention and reversal of experimental autoimmune thyroiditis with antibodies that target helper L3T4+ T cells, including targeting the helper equivalent of helper T cells may be effective in the therapy of certain autoimmune diseases of humans (See entire document, including Abstract and Discussion).

In teaching the use of phosphotyrosine phosphatase inhibitors to control or downregulate the proliferation of B cells in the treatment of autoimmune diseases such as Hashimoto's thyroiditis (e.g. column 17, A. Inhibition of Proliferation of B cells), Schieven teach that such methods can be to prevent class switching, wherein the CD40 ligand gp39 is involved (see column 19, D. Prevention of Class-Switching in Antibodies).

Given the common contribution of undesired autoantibodies and the helper T cells in autoimmune conditions, including thyroiditis and oophoritis and given the teachings of treating autoimmune diseases with anti-CD40L antibodies as taught above, the ordinary artisan would have been motivated to treat thyroiditis and oophoritis with anti-CD40L antibodies with an expectation of success that anti-CD40L antibodies would inhibit B cell activation and proliferation as well as antibody production by inhibiting helper T cells. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

3. Claims 18, 22 and 26 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Lederman et al. (U.S. Patent No. 6,592,868) in view of Tung et al. (Immunology and Allergy Clinics of North America 10 (1) : 199- 214 (1990), De Angelo et al. (J. Reprod. Immunol. 11: 41-53, 1987), Stull et al. (Cellular Immunology 117: 188-198 (1988) and Schieven(U.S. Patent No. 5,565,491).
As applied to claims 18-25 above and further in view of
Armitage et al. (U.S. Patent No. 6,264,951)

Armitage et al. teach the use of inhibiting CD40:CD40L interactions in order to inhibiting B cell proliferation and antibody formation in order to teach autoimmune diseases with soluble CD40, including CD40lg (see entire document, including columns 10-11, overlapping paragraph).

Given the common contribution of undesired autoantibodies and the helper T cells in autoimmune conditions, including thyroiditis and oophoritis and given the teachings of treating autoimmune diseases with inhibitors of CD40:CD40L interactions as taught above, the ordinary artisan would have been motivated to treat thyroiditis and oophoritis with soluble CD40, including CD40lg with an expectation of success that soluble CD40 would inhibit B cell activation and proliferation as well as antibody production by inhibiting helper T cells. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

4. No claim allowed.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 872-9306.

Phillip Gambel, PhD.
Primary Examiner
Technology Center 1600
October 20, 2003